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| 10/002,527      | 10/25/2001  | Henri Hansson        | 23544-7004          | 3275             |

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EXAMINER

PRATS, FRANCISCO CHANDLER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 04/16/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/002,527

Applicant(s)

HANSSON ET AL

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-16 are presented for examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "the reagent solution" in claim 7 renders that claim and its dependents indefinite. The term "the reagent solution" is not preceded by the recitation "reagent solution" anywhere in the claims. Moreover, the claims recite several possible solutions which might be "the reagent solution" referred to in claim 7.

The recitation "used for comparative purposes" in claim 8 is indefinite because it is not clear what process steps are encompassed by this recitation and what process steps are excluded. The metes and bounds of the recitation are not clear.

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Note that this recitation will be construed as encompassing the use of an undigested starch blank as a control.

The recitation "compared with respect to their ability to resist enzymatic degradation" in claims 9, 10, 12 and 13 is indefinite because it is not clear what is being compared to what. Because the claims fail to set forth the criteria for the comparison, it is not clear what actual process steps must be conducted to fall within the claim language.

The recitation "used to predict the enzymatic degradation behavior of starch *in vivo*" in claim 11 is indefinite because it is not clear what process steps the quoted language actually requires. Similarly, the recitation "used to predict the enzymatic degradation profile of starch *in vivo*" in claims 14-16 is also indefinite because it is not clear what process steps the quoted language actually requires. Because of the use of the passive term "use," it is not clear what process steps are required by the claims.

Lastly, note that the recitation "degradation profile" is indefinite because it is not clear what is encompassed by the claims.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10, 12, 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ring et al (Food Chemistry 28:97-109 (1988)).

Ring discloses a comparison of the resistance of raw, i.e., undigested or untreated, granular starch to digestion by pancreatic  $\alpha$ -amylase. See abstract. Specifically, Ring discloses the treatment of raw starch granules from pea, maize, wheat and potato with pancreatic  $\alpha$ -amylase at 37°C in 0.05 M phosphate buffer at pH 6.9, in 0.04% NaCl (0.0068 M), for 24 hours, wherein the extent of hydrolysis is determined colorimetrically by two methods. See page 99, fourth full paragraph ("For the physico-chemical studies . . . ."); see also page 101, last paragraph; see also Table 3 on page 102.

Because Ring discloses the enzymatic digestion of raw granular starch and the colorimetric assessment of the extent of hydrolysis according to the claimed methods, claim 1 is clearly

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anticipated by Ring. Ring clearly compares the results to the digestion of a variety of starch fractions, including those from pea, maize, wheat and potato (Table 3, page 102), as well as comparing to data from gelatinized starch fractions (Table 4, page 103), thus anticipating claims 9, 10, 12 and 13. Moreover, the stated purpose of the study was "to use *in vitro* techniques to determine how the physical for of starch polysaccharides affects their rate and extent of digestion." Page 99, top paragraph. Thus, claims 15 and 16 are clearly anticipated by the reference as well.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

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order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring et al (Food Chemistry 28:97-109 (1988)).

As discussed above, Ring discloses the treatment of raw starch granules from pea, maize, wheat and potato with pancreatic  $\alpha$ -amylase at 37°C in 0.05 M phosphate buffer at pH 6.9, in 0.04% NaCl (0.0068 M), for 24 hours, wherein the extent of hydrolysis is determined by two methods which colorimetrically assess the amount sugar released from the raw starch. See page 99, fourth full paragraph ("For the physico-chemical studies . . . ."); see also page 101, last paragraph; see also Table 3 on page 102.

Ring differs from claim 8 and its dependent claims 11 and 14 only in that Ring does not explicitly disclose the use of an undigested starch preparation as a control for measuring the color of undigested starch contacted with color-generating reagent. It would appear that such a control would necessarily have been performed. However, it cannot be truly said that the use of a control is inherent in Ring's process. Despite this, the use of an untreated control or blank in colorimetric enzyme

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assays is extremely well known in the art. Thus, the claimed use thereof must be considered obvious over the cited reference.

Ring differs from claim 2 only in the fact that Ring does not disclose the filtering step recited therein. However, in view of the fact that the undigested product, raw starch, is insoluble, the use of a separation step, such as centrifugation or the claimed filtration, to separate the insoluble reactant from the soluble product to be measured must be considered obvious since such a step would have been reasonably expected to ensure the accuracy of the measurement of the amount of product generated by the process.

Ring differs from claim 3 only in the fact that Ring does not disclose the measurement of the color at the claimed wavelength. However, the determination of a suitable wavelength for use in the colorimetric assays disclosed in Ring would have been considered a matter of routine optimization on the part of the artisan of ordinary skill, the artisan recognizing that using different wavelengths would have affected the result of the measurement process. The selection of the wavelength recited in claim 3 must therefore be considered obvious.



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Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring et al (Food Chemistry 28:97-109 (1988)) in view of Bernfeld (Methods Enzymol. 1:149-159 (1955)).

As discussed above, Ring discloses the treatment of raw starch granules from pea, maize, wheat and potato with pancreatic  $\alpha$ -amylase under the claimed process conditions, thereby anticipating and/or rendering obvious claims 1-3 and 8-16. Ring differs from claims 4-6 and their dependent claim 7 in that Ring does not use 3,5 dinitrosalicylic acid as the color-generating agent for determining the amount of sugar released from the raw starch granules.

However, Bernfeld clearly discloses that 3,5 dinitrosalicylic acid is a suitable reagent for determining the amount of sugars released from starch by  $\alpha$ -amylase digestion. See pages 149-150. Moreover, Bernfeld clearly discloses that the assay method using 3,5 dinitrosalicylic acid is advantageous in that it is "simple, reliable and rapid." Page 149. As an aside, note Bernfeld's disclosure of the use of a blank for control or comparison purposes. See sentence spanning pages 149-150. Thus, the artisan of ordinary skill, recognizing from Bernfeld the advantages of using the assay method disclosed therein, clearly would have been motivated to have used the 3,5

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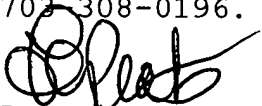
dinitrosalicylic acid as the colorimetric agent for determining the degree of starch digestion in the methods of Ring. A holding of obviousness is therefore required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
February 14, 2003